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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 06/11/2008
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/750,139
Filing Date: June 03, 2004
Appellant(s): DESNOYER ET AL.

Zhaoyang Li, Ph.D.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/03/2008 appealing from the Office action mailed 10/10/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 03022323	Pacetti	3-2003
WO 98/32398	Roby	7-1998
US 2002/0107330	Pinchuk	8-2002

(9) Grounds of Rejection

**The following ground(s) of rejection are applicable to the appealed claims:
Claims 1-3 and 5-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by appellants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by appellants in IDS filed 11/06/2006).**

Pacetti discloses a coating for reducing the rate release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent. See abstract. The polymers include polyurethanes with a polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid), styrene-ethylene-styrene block copolymer, polytetrafluoroethylene ect. See [0020]-[0021] and claims 11,16-17. The therapeutic agents included anti proliferative-substances, antibiotics, paclitaxel ect. See [0028]. Regarding the limitation that the implantable device is applied to a solution of PEA and a low surface energy, surface blooming polymer, Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition. See [0023]. Regarding claims 45-52 Pacetti discloses several methods of using the coated stents including treatment of obstructions caused by tumors and for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle tissue cells, thrombosis and restenosis. See [0032].

Pacetti does not disclose the use of PEA in combination with the crystalline polymers (same as low surface energy polymer or low surface energy, surface blooming polymer), to produce a coating containing a therapeutic for a stent.

Roby discloses the preparation of polyesteramides and surgical devices fabricated from them. See abstract and pag 1 lin 1-21. Roby is used mostly for the disclosure within that polyesteramides can be used as a coating for surgical devices and the polyesteramide surgical devices could also incorporate therapeutic agents such as antimicrobial agents. See pag 6 lin 3-pag 8 lin 18. The polyesteramide compositions could also be blended with other absorbable or non-absorbable compositions. Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties. Regarding claims 53-58 it is obvious that since both the coatings described in Pacetti and Roby are used for medical devices for use in the body the coating would be biologically benign and since the combination of the coatings described in the references above are the same as applicants claimed invention it is also obvious that the coatings would have the same properties, including being biologically benign. Regarding appellant's proviso that the low surface energy, surface blooming polymer or polymer additive comprises a PEA miscible block or a PEA miscible backbone, since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Where the

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claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Pacetti disclosed the use of both the same low surface energy polymers and low surface energy, surface blooming polymers for a stent coating containing a therapeutic as appellants claims while Roby disclosed that coatings for surgical devices containing PEA and therapeutics was already well known in the art at the time of the invention. The motivation to combine the above documents would be to produce and use a coated stent in which the coating comprised a therapeutic, PEA and a highly crystalline hydrophobic polymer (same as applicants low surface energy polymer). The advantage of such a coating would be that the combination would provide a biologically absorbable coating with desirable mechanical properties from the PEA polymer disclosed in Roby and a controlled release of the therapeutic from the crystalline polymers disclosed in Pacetti. One of ordinary skill in the art would have a reasonable expectation of success in combining the PEA polymers of Roby with the polymers of Pacetti because both polymers are disclosed as useful in the same field of endeavor being polymers useful as coatings for a stent. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al. (WO 98/32398 A1, cited previously) in view of Pinhcuck et al. (US 2002/0107330).

Roby was disclosed previously in the office action dated 06/12/2007. Roby discloses PEA polymers useful in coating surgical devices. Roby does not disclose the low surface energy polymers as recited in claim 4.

Pinchuck discloses coatings over an intravascular or intervascular medical device comprising a biocompatible polymer that comprises an A block and a B block, the A-block includes polyolefin monomers that when polymerized will form an alkyl chain and a B-block that includes monomers of methacrylates. See abstract and [0027]-[0036]. Pinchuck also discloses that the medical devices can further comprise a copolymer that includes blocks of the following polymers polycaprolactone, polyglycolic acid, siloxane polymers and the like. See [0016]. Either of the copolymers described above would meet appellant's claimed low surface energy polymer as recited in claim 4.

Thus the claimed invention would have been *prima facie* obvious since all the claimed elements such as PEA and the copolymers of claim 4 were known to be useful in coating medical devices and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

(10) Response to Argument

Response to arguments over Roby in view of Pinhcuck.

Appellants assert that Roby does not describe or teach using a PEA polymer blend to form a coating nor does Roby recognize the properties of a coating which includes PEA can be improved by using a low surface energy, surface blooming polymer as defined by claim 4. Appellants also assert that block copolymer of Pinhcuck is clearly different than the low surface energy, surface blooming polymer as defined in claim 4, notably appellants assert Pinhcuck does not teach the A component. Appellants also assert that Pinhcuck does not recognize that the properties of a coating including PEA can be improved by using a low surface energy, surface blooming polymer as defined by claim 4.

The examiner respectfully disagrees with the above assertions by appellants. Firstly in regards to appellants assertion that neither Roby or Pinhcuck disclose the properties of a blend of PEA and a low surface energy surface blooming polymer, since appellants claims were rejected over a combination of two references each individual reference does not have to disclose all of appellants claimed limitations on its own merit. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As clearly described in the rejection filed 10/10/2007 since both Roby and Pinhcuck are obviously combinable and the combination teaches all of appellants claimed limitations the claims are prima facie obvious. Regarding appellant's assertion that Pinhcuck does not describe the same claimed low surface energy polymer, clearly

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as noted in the previous office action Pinhcuck discloses the use of an A-B block copolymer that meets appellants claimed block copolymer. The blocks could contain monomers of methacrylate (meets poly(methacrylate of appellants claimed group A within claim 4) and polyolefin monomers that when polymerized will form an alkyl chain (meeting appellants claimed group B within claim 4). Furthermore as noted in the previous office action Pinhcuck outlines the use of other copolymers that can include blocks of polycaprolactone, polyglycolic acid (both meet appellants claimed group A within claim 4) and siloxane polymers (meets appellants claimed group B within claim 4). Thus clearly Pinhcuck discloses the use of copolymers that are the same as appellants claimed low surface energy, surface blooming polymers, since the polymers are essentially the same as appellants claimed copolymer it is inherent that the same polymer will have the same properties including appellants claimed low surface energy and surface blooming effect.

Response to arguments over Pacetti 2 in view of Roby.

Appellants assert that Pacetti does not describe a coating that includes PEA and a low surface energy, surface blooming polymer nor does Pacetti recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy surface blooming polymer. Appellants as stated above assert that Roby does not disclose a device composition that comprises PEA and a low surface energy surface blooming polymer nor does the reference recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming polymer.

The examiner respectfully disagree with appellants assertions above. As clearly detailed in the previous office actions filed 10/10/2007 and 06/12/2007 Pacetti clearly discloses crystalline polymers including polyurethanes with a polydimethylsiloxane soft segments and poly(vinylidene fluoride-co-methacrylic acid) both of which are within appellants claimed scope of a low surface energy, surface blooming polymers. Thus since the polymers of Pacetti are essentially the same as appellants claimed copolymer it is inherent that the same polymer will have the same properties including appellant's claimed low surface energy and surface blooming effect. Regarding appellant's assertion that neither Pacetti nor Roby disclose the properties of a blend of PEA and a low surface energy surface blooming polymer, since appellant's claims were rejected over a combination of two references each individual reference does not have to disclose all of appellants claimed limitations on its own merit. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As clearly described in the rejection filed 10/10/2007 since both Pacetti and Roby are obviously combinable and the combination teaches all of appellant's claimed limitations the claims are prima facie obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W Rogers, Ph.D./

Examiner, Art Unit 1618

Conferees:

Michael Hartley, SPE

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617